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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,310	08/25/2000	Paul B. Fisher	62943/JPW/JML	6406

7590

07/13/2005

Lisa B. Kole
Baker Botts L.L.P.
30 Rockefeller Plaza
New York, NY 10112

EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/648,310

Applicant(s)

FISHER ET AL.

Examiner

MISOOK YU, Ph.D

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54,56,58,64,70,72,74 and 80 is/are rejected.
- 7) ☒ Claim(s) 55,57,59-63,65-69,71,73,75-79 and 81-85 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/20/05</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Exhibit A</u> . |

DETAILED ACTION

Applicant's submission (amendment and declaration) filed on 04/20/2005 is acknowledged.

Claims 54-85 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Office action contains new grounds of rejection.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claims 58-69, and 74-85 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated host cell for protein expression purposes, does not reasonably provide enablement for host cell in gene therapy or any other in vivo use is withdrawn because applicant argument is persuasive in light of Dr. Fisher's Declaration.

Allowable Subject Matter

The indicated allowability of claims 54-57, and 70-73 is withdrawn in view of the art rejection below.

The Following are New Grounds of Rejections

Claim Rejections - 35 USC § 102

Claims 54, 56, 58, and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank accession number AA891725 (a copy provided on 1/30/2003, 08-JAN-1999). This is reinstatement of the art rejection in the Office action mailed on 1/30/2003.

The claimed invention is drawn to an isolated nucleic acid comprising a nucleic acid encoding SEQ ID NO: 2 (claim 54), vector containing said nucleic acid (claim 56), a host cell containing said nucleic acid (claim 58), host cell containing said vector (claim 64).

Applicant argued that the prior art of record is an EST sequence, and there is no teaching of operatively linking an enhancer element to the EST.

These arguments have been fully considered. However, the Office reinstates the rejection because the isolated nucleic acid disclosed in GenBank accession number AA891725 comprises a nucleic acid encoding SEQ ID NO: 2 as claimed in the instant claim 54. GenBank accession number AA891725 also discloses that the nucleic acid is in a pT7T3Pac between the EcorR1 and NotI. Bonaldo et al (1996, Genome Research, vol. 6, pages 791-806) are cited to present an evidence that the nucleic acid of the prior art is operatively linked to a promoter. Bonaldo et al., at Figure 6 at page 802 disclose that pT7T3Pac that the prior art nucleic acid is inserted in inherently has T7 promoter and the EcorR1 and Not I is in the polylinker region flanked by T7 and T3 promoter. Therefore it is the Office position that the nucleic acid insert is operatively linked to a promoter. In addition, GenBank accession number AA891725 discloses the nucleic acid of GenBank accession number AA891725 is from clone RKIAG02. Voet et al.,(1990, Biochemistry, John Wiley & Sons, page 837) are cited to demonstrate the term "clone" inherently include a host cell, i.e. an organism that contains the vector containing the nucleic acid of interest.

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Claims 70, 72, 74, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank accession number N39717 (22-JAN-1996).

The claimed invention is drawn to an isolated nucleic acid comprising a nucleic acid encoding SEQ ID NO: 4 (claim 70), vector containing said nucleic acid (claim 72), a host cell containing said nucleic acid (claim 74), host cell containing said vector (claim 64), and host cell containing vector of claim 72 (claim 80).

GenBank accession number N39717 discloses an isolated nucleic acid comprising a nucleic acid encoding instant SEQ ID NO:4. Note the attached Exhibit A (a sequence alignment of the nucleic acid encoding the instant SEQ ID NO:4 against the nucleic acid disclosed in GenBank accession number N39717) showing the nucleic acid of GenBank accession number N39717 inherently encodes the entire instant SEQ ID NO:4, i.e. 100 % identical. The EST insert encoding the instant SEQ ID NO:4 is in pT7T3Pac, which is designed to put a cDNA insert operatively to a promoter. Note Bonaldo et al (cited above). As for host cell, the vector containing the cDNA insert is in a ampicillin resistant DH10B.

Conclusion

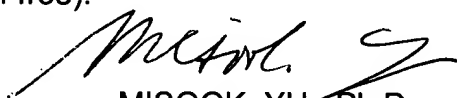
The claims depend on the rejected base claims are objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MISOOK YU, Ph.D
Examiner
Art Unit 1642

AUTHORS
 Kim, N.S., Hahn, Y., Oh, J.H., Lee, J.Y., Ahn, H.Y., Chu, M.Y., Kim, M.R.,
 Kim, Y.S., Cheong, J.E., Sohn, H.Y., Kim, J.M., Park, H.S., Kim, S. and
 21C Frontier Korean EST Project 2001
 Unpublished (2002)
COMMENT
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 Email: yongsung@mail.kribb.re.kr
 Plate: 30 row: F column: 01
 High quality sequence stop: 477.
 Location/Qualifiers

FEATURES
 source
 1. 477
 /organism="Homo sapiens"
 /mol_type="mRNA"
 /db_xref="taxon:9606"
 /clone="S38NU16-30-P01"
 /sex="F"
 /tissue_type="Ascites"
 /cell_type="Lymphoblast-like"
 /cell_line="SNU-16"
 /lab_host="Top10P"
 /clone_lib="S38NU16"
 /notes="Organ: Stomach; Vector: pTZ19RP1; Site 1: EcoRI; Site 2: NotI; The poly (A) + RNA was dephosphorylated with bacterial alkaline phosphatase (BAP) and then decapped with tobacco acid pyrophosphatase (TAP). The decapped intact mRNA was ligated with DNA-RNA linker including EcoRI. I site by treatment of T4 RNA ligase and the first strand cDNA was synthesized from oligo dt-selected mRNA by priming with dt-tailed vector. The dt-tailed vector was adjusted to have about 50ng. The cDNA vector was circularized with E. coli/DNA ligase after digestion of EcoRI which site is also included in vector. An RNA strand converted to a DNA strand by Okayama-Berg method. The obtained cDNA vectors were used for transformation of competent cells E. coli Top10P by electroporation method. The cDNA libraries constructed by this method are full-length enriched cDNA library."

FEATURES
 source

ALIGNMENT SCORES:
 Pred. No.: 2,556-45 Length: 477
 Score: 410.00 Matches: 81
 Percent Similarity: 100.00% Conservatives: 0
 Best Local Similarity: 100.00% Mismatches: 0
 Query Match: 100.00% Indels: 0
 DB: 12 Gaps: 0

US-09-648-310-4 (1-81) x BW752941 (1-477)
 QY 1 MetAsnValAspHisGluValAsnLeuValGluGluLeuHisArgLeuGlySerLys 20
 DB 139 ATGAATGTGATCAGCAGGTTAACTCTTAGTGGAGAAATTCATCGTTGCTCAAA 198
 QY 21 AsnAlaAspGlyValLeuSerValValPheGlyValLeuPheArgAspLysCysVal 40
 DB 199 AATGCTGATGGAAGTAAAGCTGAAATTTGGGCTCTTCCTGATGATTAATGTGCC 258
 QY 41 AsnLeuPheGluAlaLeuValGlyThrLeuValAlaAlaLysArgLysLeuValThr 60
 DB 259 AACCTCTTTGAAGCATTTGATAGAACTCTTAAGCTCAAAACGAGGAGAGATTGTAACA 318
 QY 61 TyrProGlyLeuLeuLeuGlnGlyValHisAspValAspLeuLeuGln 80
 DB 319 TATCCAGGAGAGCTGCTTCTGCAAGGTGTCATGATGATGATGATGATGATGATGCA 378
 QY 81 Asp 81
 DB 379 GAT 381

RESULT 3
 N39717
 LOCUS
 DEFINITION
 Yx92d07.x1 Soares melanocyte 2MbHM Homo sapiens cDNA clone
 IMAGE:269197 5', mRNA sequence.

RESULT 2
 BUI99007
 LOCUS
 DEFINITION
 ACCESSION
 VERSION
 KEYWORDS
 SOURCE
 ORGANISM
 Homo sapiens (human)
 Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
 1 (bases 1 to 480)
 Xu, X., Gu, J., Liu, P., Qu, J., Zhao, M., Li, Y., Huang, Q., Zhou, J.,
 Song, H., Gu, Y., Yang, Y., Gao, G., Xiao, H., Li, N., Qian, B., Gao, X.,
 Cheng, Z., Xu, S., Gu, W., Tu, Y., Jia, J., Fu, G., Ren, S., Zhong, M.,
 Lu, G., Cheng, Z., and Han, Z.
 Homo sapiens cDNA DCB clones
 Unpublished (2000)
 Contact: Zeguang Han
 Chinese National Human Genome Center at Shanghai
 351 Guo Shoujing Road, Zhangjiang Hi-Tech Park, Pudong, Shanghai
 201203, P. R. China
 Tel: 86-21-50801919 (ex.45)
 Fax: 86-21-50801922
 Email: hanzeg@chgc.sh.cn.
 Location/Qualifiers
 1. 480
 /organism="Homo sapiens"
 /mol_type="mRNA"
 /db_xref="taxon:9606"
 /cell_type="dendritic cells"
 /dev_stage="mature"
 /lab_host="BM25.5"
 /clone_lib="DCB"
 /note="Vector: pTriplex2, Site_1: sfIIA, Site_2: sfIIB"

ORIGIN

ALIGNMENT SCORES:
 Pred. No.: 2,596-45 Length: 480
 Score: 410.00 Matches: 81
 Percent Similarity: 100.00% Conservatives: 0
 Best Local Similarity: 100.00% Mismatches: 0
 Query Match: 100.00% Indels: 0
 DB: 13 Gaps: 0

US-09-648-310-4 (1-81) x BUI99007 (1-480)
 QY 1 MetAsnValAspHisGluValAsnLeuValGluGluLeuHisArgLeuGlySerLys 20
 DB 189 ATGAATGTGATCAGCAGGTTAACTCTTAGTGGAGAAATTCATCGTTGCTCAAA 248
 QY 21 AsnAlaAspGlyValLeuSerValValPheGlyValLeuPheArgAspLysCysVal 40
 DB 249 AATGCTGATGGAAGTAAAGCTGAAATTTGGGCTCTTCCTGATGATTAATGTGCC 308
 QY 41 AsnLeuPheGluAlaLeuValGlyThrLeuValAlaAlaLysArgLysLeuValThr 60
 DB 309 AACCTCTTTGAAGCATTTGATAGAACTCTTAAGCTCAAAACGAGGAGATTGTAACA 368
 QY 61 TyrProGlyLeuLeuLeuGlnGlyValHisAspValAspLeuLeuGln 80
 DB 369 TATCCAGGAGAGCTGCTTCTGCAAGGTGTCATGATGATGATGATGATGATGCA 428
 QY 81 Asp 81
 DB 429 GAT 431

RESULT 3
 N39717
 LOCUS
 DEFINITION
 Yx92d07.x1 Soares melanocyte 2MbHM Homo sapiens cDNA clone
 IMAGE:269197 5', mRNA sequence.

Exhibi A
 page 1 of 2

